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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,705	07/10/2003	Mike Zeeff	MAR-021133	1561
30981	7590	06/01/2004	EXAMINER	
King & Jovanovic, PLC 170 College Avenue SUITE 230 HOLLAND, MI 49423			FERNSTROM, KURT	
			ART UNIT	PAPER NUMBER
			3712	

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,705

Applicant(s)

ZEEFF, MIKE

Examiner

Kurt Fernstrom

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/7/03.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims contain several instances of indefinite terminology. Claims 1, 2, 7, 8, 9, 10, and 13 recite a "suppression component". The specification does not adequately define the term to enable one of ordinary skill to understand what is being claimed, or how this component operates to suppress something. Claim 6 contains the term "approximately", which renders the claim indefinite. Applicant is attempting to claim a range, without defining the boundaries of the range. Claim 9 uses the term "optionally", which makes it unclear whether these steps are being positively recited as part of the claimed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-3, 5-9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider in view of Lee. Schneider discloses in column 3, line 43 to column 4, line 66 an artificial bone comprising a substrate material comprising a plurality of closed cells. Schneider fails to disclose a suppression component or an x-ray component. Lee discloses in column 4, lines 29-37 a bone simulating material which includes an x-ray component therein. It would have been obvious to one of ordinary skill in the art to modify the device of Schneider by providing an x-ray component for the purpose of making the material detectable using an x-ray. With respect to claims 2 and 13, it is not clear what is meant by a "suppression component", as discussed above. With respect to claim 3, Schneider discloses the use of polyurethane. With respect to claim 5, Lee discloses the use of barium. With respect to claim 6, the claim is indefinite as discussed above. Also, the percentage claimed is an obvious variation on Lee, which does not disclose a specific percentage. There does not appear to be any particular functional purpose to the claimed percentage. With respect to claims 7 and 8, claim 1 does not positively recite that the invention comprises a suppression component. Therefore, claims 7 and 8 also fail to explicitly recite a suppression component, as they merely provide further limitations to one member of the Markush group of claim 1. Since Schneider as viewed with Lee discloses the other member of the Markush group, they read on claims 7 and 8.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider in view of Lee, and further in view of Biermann. Schneider as viewed in combination with Lee discloses all of the limitations of the claims with the exception of the use of

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polyethylene. This material is known in the art, as disclosed for example in column 2, lines 33-66 of White. It would have been obvious to one of ordinary skill in the art to modify the device of Schneider as viewed in combination with Lee by providing polyethylene for the purpose of creating a device which more closely resembles an actual human bone.

Claims 9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider in view of Lee, and further in view of White. Schneider as viewed in combination with Lee discloses all of the limitations of the claims with the exception of the steps of placing the substrate material into a mold, curing it and finishing it. These steps are known in the art, as disclosed for example by White. It would have been obvious to one of ordinary skill in the art to modify the device of Schneider as viewed in combination with Lee by providing the claimed steps for the purpose of creating a device which more closely resembles an actual human bone.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider in view of Lee and White, and further in view of Sumita. Schneider as viewed in combination with Lee and White discloses all of the limitations of the claim with the exception of the use of elevated pressure within an autoclave. This step is known in the art, as disclosed for example in column 3, lines 25-41 of Sumita. It would have been obvious to one of ordinary skill in the art to modify the device of Schneider as viewed in combination with Lee and White by providing an autoclave having elevated pressure for the purpose of creating a device which more closely resembles an actual human bone.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Miyata, Draenert, Trella and Wang disclose artificial bone devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kurt Fernstrom whose telephone number is (703) 305-0303. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Derris Banks can be reached on (703) 308-1745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KF
May 25, 2004

Kurt Fernstrom
Kurt Fernstrom